

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

**IN RE: ETHICON INC., PELVIC REPAIR
SYSTEM PRODUCTS LIABILITY LITIGATION**

MDL No. 2327

2:12-md-02327

THIS DOCUMENT RELATES TO:

HON. JOSEPH R. GOODWIN

*Fox et al. v. Ethicon, Inc. et al.,
No. 2:12-cv-0878*

*Ridgley v. Ethicon, Inc., et al.,
No. 2:12-cv-0311*

**MEMORANDUM IN OPPOSITION TO DEFENDANTS’
MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF
KONSTANTIN WALMSLEY, MD**

I. INTRODUCTION.

Defendants’ motion should be denied. Dr. Walmsley is a board certified urologist experienced in treatment of mesh complications. He has clinical experience with a variety of options to treat SUI – including mid urethral slings (synthetic and non-synthetic) and autologous fascial slings. He has reviewed medical literature. Dr. Walmsley applied his clinical experience and review of the literature to form the opinions Defendants take issue with. These opinions rest on a reliable foundation of clinical experience bolstered by references to medical literature.

II. LEGAL STANDARD.

Under Fed. R. Evid. 702, “expert testimony is admissible if the expert is ‘qualified...by knowledge, skill, experience, training, or education,’ and if his testimony is (1) helpful to the trier of fact in understanding the evidence ...; (2) based on sufficient facts or data; and (3) the product

of reliable principles and methods that (4) have been reliably applied ‘the facts of the case.’” *Carlson v. Boston Scientific Corp*, 2015 1931311 at * 2 (S.D.W.Va).

This Court has previously considered Dr. Walmsley’s opinions regarding safer procedures and mesh complications in the context of the Pinnacle device. *Eghnayem v. Boston Scientific Corp.*, 57 F.Supp.3d 658, 714-715 (S.D.W.Va. 2014). This Court found “simply because Dr. Walmsley believes that polypropylene mesh devices are functional products does not mean he cannot opine that there were safer alternatives.” *Id* at 715. Regarding Dr. Walmsley’s opinions on mesh complications in *Eghnayem* the Court found where his opinions were bolstered to references to scientific literature they were reliable. *Id* at 714.

Dr. Walmsley’s proffered opinions on IFU adequacy and surgical alternatives rest on a reliable foundation of clinical experience bolstered by literature. Further, these opinions will assist the jury in this case.

III. ARGUMENT & AUTHORITY

A. Dr. Walmsley’s IFU Adequacy Opinion is Reliable.

Dr. Walmsley has put forth the opinion the TVT IFU was inadequate to facilitate informed consent at the times when Plaintiffs were implanted. Ex. A; B. This Court has permitted clinical practitioner experts to testify on the accuracy and completeness to the IFU. *See Carlson v. Boston Scientific Corp*, 2015 1931311 at * 15-16 (S.D.W.Va) (permitting Dr. Shull to testify regarding Uphold IFU); *Huskey v. Ethicon, Inc.*, 29 F.Supp.3d 691, 719-20 (S.D.W.Va 2014) (finding Dr. Blaivas qualified to testify regarding TVT-O IFU); *In re Yasmin and Yaz (Drospirenone) Marketing, Sales Practices and Products Liability Litigation*, 2011 WL 6301625 at * 11 (S.D.Ill) *citing In re Diet Drugs Prods. Liab. Litig.*, 2000 WL 876900 (E.D.Pa) (finding “doctors are fully qualified to opine on the medical facts and science regarding the risks and benefits of [drugs]...and

to compare that knowledge with what was provided in the text of labeling and warnings.”). Dr. Walmsley’s proffered opinion on the TVT IFU is no different. His opinion on the IFU compares the risks of the TVT based on his clinical experience and review of the literature, with the text of the label.¹

1. Dr. Walmsley’s Opinions Are Bolstered by References to Literature. (Resp. to Def. Mem at 2-4)

Contrary to Defendants allegation that Dr. Walmsley solely relied on his clinical experience to form his IFU opinions, Dr. Walmsley relied on medical articles, his clinical experience, the TVT IFU, depositions, medical records, and an opinion article on informed consent in forming his opinion. Ex. A; B. Dr. Walmsley testified in the *Fox* matter:

Let me ask you, what did you review before drafting your report, your final report? What did you rely on to draft your report?

A. So I relied upon the medical records that are stated in the report. There were a handful of articles that I used as references in terms of forming my opinion. I had the IFU for the TVT device that dated back to the time that it was implanted. And also an informed consent document produced by the AMA.

Deposition of Dr. Walmsley in *Fox* at 18:10 to 18:19. *See also* Deposition of Dr. Walmsley in *Ridgley* at 17:22 to 18:25, where Dr. Walmsley describes the materials he relied upon in drafting his report in the *Ridgley* case.

Specifically, Dr. Walmsley, in the *Fox* case, read and relied on the deposition of implanting physician Dr. Warner in forming his opinions. At Dr. Warner’s deposition, a 1999 study by Dr. Klinge was attached as an exhibit and discussed extensively. Ex. C. This study looked at foreign body reaction to mesh including Prolene mesh and concluded “there was evidence of long term wound complications as a result of persistent foreign body reactions” *Id* at 665. This literature

bolsters Dr. Walmsley's opinion regarding the IFU's description of foreign body response to Prolene mesh.

Dr. Walmsley also considered a 2014 study by Sara Abbott, MD. Ex D. This study concludes "most of the women who seek management of synthetic mesh complication after POP or SUI surgery have severe complications that require surgical intervention." *Id* at 163.e1. The authors of the Abbott study provide "We can only observe that when [complications] occur, the nature of the complication is usually severe and often requires surgical intervention. Nonetheless, this information is helpful in depicting worse-case scenario outcomes, which can be central to informed consent discussions and decision making."² *Id* at 163.e8. This literature bolsters Dr. Walmsley's opinion that difficulty in mesh removal should be discussed to facilitate informed consent. Ex. A; B. The study confirms his clinical experience in removing mesh which existed at the time of each implantation.

Dr. Walmsley's opinion on IFU adequacy is supported by his clinical experience and his clinical experience is reinforced by the medical literature. This adds reliability to Dr. Walmsley's IFU opinion.

2. Dr. Walmsley Is Not A Regulatory Expert.

Defendants cite to the *Tyree v. Boston Scientific Corp.*, 54 F.Supp.3d 501, 543 (S.D.W.Va. 2014) and *Sanchez v. Boston Scientific Corp.*, 2014 WL 4851989 at * 39 (S.D.W.Va) as authority to exclude Dr. Walmsley here. The portions of the cases cited address the opinions of Dr. Pence. Dr. Pence is a regulatory expert and the Court excluded her opinions finding "the only basis for Dr. Pence's opinions on the adequacy of BSC's product labeling is violation of the FDCA and

² Dr. Walmsley considered numerous other studies in addition to the Klinge and Abbott articles. Ex. A and Ex. B.

FDA regulations. Such a violation, however, is not probative of the claims at issue.” *Tyree*, 54 F.Supp 3d at 543 *citing Sanchez*, 2014 WL 4851989 at *35-36.

Dr. Walmsley is not opining on FDA regulations to conclude Ethicon’s labeling is inadequate. Rather, Dr. Walmsley’s opinions are linked to his clinical experience and review of literature vs. the text of the IFU. The findings in *Sanchez* and *Tyree* regarding Dr. Pence do not apply to Dr. Walmsley’s IFU opinion because the foundation of their opinions is different (FDA regulations vs. clinical experience)

B. Alternatives in the TVT IFU. (Resp. to Def. Mem. at pg 4-7)

Defendants assume Dr. Walmsley intends to proffer an opinion that alternative treatments for SUI should have been included in the TVT IFU. Ex. L at pg 4. According to Defendants, this opinion would be contrary to the law. *Id.*

This argument sets up a straw man and knocks it down. Dr. Walmsley does not have an opinion that alternatives should have been discussed in the IFU. His opinion is simply: “Safer alternative designs and procedures existed in 2002 that have a lesser risk of erosion and dyspareunia with substantially equivalent efficacy.” Ex. A. *See also* Affidavit of Konstantin Walmsley, MD, attached hereto as Ex. E. To the extent Dr. Walmsley’s opinion can be interpreted as Defendants suggest, Plaintiffs agree not to elicit any opinion testimony regarding a comparison between the TVT and non-TVT procedures in the IFU.

IV. CONCLUSION

For the reasons above, and more fully set forth in the individual response in the *Fox* and *Ridgely* cases, Defendants Motion to Exclude the Opinions and Testimony of Dr. Walmsley should be denied.

RESPECTFULLY SUBMITTED,

Dated: May 9, 2016

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing instrument has been forwarded to all counsel of record, via hand delivery, certified mail or facsimile, in accordance with the Federal Rules of Civil Procedure, on May 9, 2016.

/s/ Rick Barreca
Attorney for Plaintiffs